

Charter on Access to Health in Developing Countries

Fake Medicines

July 2014

Our Promise

Merck KGaA, Darmstadt, Germany is a leading company for innovative and top-quality high-tech products. As the oldest pharmaceutical and chemical company in the world, founded in 1668, we have developed countless innovations that improve people's lives.

Unfortunately, millions of people still lack access to the benefits of modern health care innovations in developing countries.¹ We are committed to improving the health of underserved populations, who lack access to health solutions including prevention, diagnostics and treatments. By enhancing availability, accessibility and affordability of our products, and by raising awareness in communities, we work to provide quality, safe health solutions for all.

We have a long-standing commitment to ensuring pharmaceutical safety and quality. Emanuel Merck cemented the company's position in 1851 with the claim, "I shall always guarantee the purity of my preparations". Unfortunately, the growing threat of fake medicines undermines efforts to assure access to safe and quality health care. This is especially true in developing countries where the prevalence of these medicines is highest. Fake medicines can result in treatment failure. In extreme cases they can be fatal. As a global health community, we have a long road ahead of us in ensuring patient safety. We at Merck KGaA, Darmstadt, Germany are committed to ensuring patients receive effective drug therapy and are aware of the dangers of fake medicines. We raise awareness, build capacity and partner with key stakeholders to sustainably combat fake medicines.

¹ For a full list of developing countries, refer to Merck KGaA, Darmstadt, Germany's Access to Health Charter, Our Approach.



Access to Health in Developing Countries

An estimated 1.3 billion people have no access to effective and affordable health care. According to the World Health Organization (WHO), developing countries bear 93% of the world's disease burden, yet account for only 18% of world income and 11% of global health spending.² Providing access to health in these countries is a complex challenge. Improving access involves researching, developing and refining health solutions, creating efficient health systems and distribution channels, offering products at affordable prices and empowering health workers and patients. All health stakeholders, both public and private, must pool their efforts to overcome health access barriers.

In contributing to providing access to health in developing countries, we work at the interface of medicines, diagnostics, nutritional supplements and chemicals, utilizing our local and global presence, expertise and core competencies. For instance, we produce a range of essential medicines that are included in the WHO Essential Medicines List. These medicines are currently distributed in 74 developing countries including 35 countries in Africa, 18 in Asia and 12 in Latin America. Our products are available in nearly two thirds of Least Developed Countries (LDCs) including countries such as Afghanistan, Benin, Burkina Faso, Ethiopia, Haiti, Mali, Myanmar, Nepal, Senegal, and Sudan.

The Risks of Fake Medicines in Developing Countries

Every day, millions of people take medicines to treat conditions from the common cold to life-threatening diseases like cancer. For most patients, these medicines help make them healthier. Regrettably, a growing number of people receive fake medicines – particularly in developing countries.³ The International Policy Network estimates that each year 700,000 deaths are caused by fake drugs for malaria and tuberculosis– diseases most prevalent in developing countries.⁴ According to the WHO, about 100,000 deaths in Africa are linked to the counterfeit drug trade yearly.⁵ Fake medicines may also lead to collective risks for a population, such as the emergence of drug-resistance to antibiotics or anti-malarials used to treat infectious diseases.

More than 30% of medicines on sale are fake in some countries in Africa, Asia and Latin America. The WHO estimates that 50% of the medicines sold by illegal internet pharmacies are counterfeits. The full scope of this global problem is difficult to establish due to under-reporting and lack of enforcement, as the trade in fake medicines is highly lucrative and hard to trace. But it is clear that access to effective, quality health solutions is severely compromised by the fake medicine businesses.

² Denis Drechsler and Johannes Jütting, Private Health Insurance for the Poor in Developing Countries? 2005

³ About 60% of all known cases are located in developing countries. Source: WHO, General information on counterfeit medicines

⁴ IPN Press release, Fake drugs kill over 700,000 people every year - new report, <http://archive.is/ipW8i>

⁵ Africa Renewal, Counterfeit drugs raise Africa's temperature, 2013



Fighting Fakes

Safety, quality, efficacy and security remain at the core of our commitment. We perform thorough and regular checks on our distribution network and supply chain partners to ensure compliance with our requirements. We are a leader in the pharmaceutical industry's attack on fake medicines: we launched the first track-and-trace system in the United States. We are committed to stopping criminals that threaten the well-being of our patients. As a result we work closely with domestic, regional and international law enforcement agencies to identify and persecute falsified medicines criminal activities.

Our Commitment to Quality, Safety and Security

All of our products comply fully with global Good Manufacturing Practices (GMPs) and Good Distribution Practices (GDPs). We combat counterfeiters through initiatives such as:

- **Tamper-evidence:** with the development, testing, and introduction of tamper-proof seals for selected products
- **Authentication protocols:** most notably with a Merck KGaA, Darmstadt, Germany-proprietary optically variable, color-shifting pigment
- **Identification systems:** for which we have launched a track-and-trace program on selected products worldwide

Our Merck KGaA, Darmstadt, Germany Anti-Counterfeiting Operational Network (MACON) is a cross-functional group of internal experts on law, intellectual property, product security, supply chain quality assurance and corporate security. MACON supervises and implements anti-counterfeiting measures globally for all our products. The group monitors global markets, internet activity and legislative developments. Any incidents are promptly reported to the relevant law enforcement and regulatory bodies.

We believe that fake medicines, regardless of their manufacturer, put patients' lives at risk. We therefore support a variety of initiatives that go beyond our products. We work with partners to raise awareness about fake medicines and to discourage counterfeiters. For example, we help educate patients about the dangers associated with unlicensed pharmacies and the signs of product tampering.

Working hand-in-hand with government authorities and health care professionals, we help assess the authenticity of medicines and prosecute those responsible for fakes to the fullest extent of the law.



Our support to the Global Pharma Health Fund

We are proud to be the founder and exclusive supporter of the Global Pharma Health Fund (GPHF), a charitable organization that has improved health care and medicines supply in developing countries since 1985. As part of its portfolio, GPHF has developed the GPHF-Minilab™, a mobile unit that can be used for rapid drug quality verification and fake medicine detection. The size of two suitcases, the GPHF-Minilab™ provides rapid, simple and inexpensive tests to verify the identity and content of 70 compounds. The GPHF-Minilab particularly focuses on verifying medicines for infectious diseases. In response to emerging needs and to requests from developing country governments, we continually invest in the development of testing methods for new compounds.

GPHF has donated or provided at-cost more than 650 GPHF-Minilabs™ to organizations in over 85 countries, located predominantly in Africa and Asia. Since 2012, we have made donations to Ministries of Health and National Regulatory Authorities in thirteen developing countries. These Minilab donations help strengthen health systems and enhance healthcare capacity. Data generated by the program has prompted WHO global drug alerts.

The success of the GPHF lies in our ability to catalyze collaboration and partnerships with governments, non-governmental organizations and faith based organizations. For example, we work with the Ecumenical Pharmaceutical Network (EPN) and the Promoting the Quality of Medicines (PQM) programme run by the United States Pharmacopeia (USP) and United States Agency for International Development (USAID).

In addition, GPHF has recently formalized a partnership with the Ghana-based Center for Pharmaceutical Advancement and Training (CePAT). Through this collaboration we will build local and regional capacity in pharmaceutical quality assurance throughout sub-Saharan Africa. The GPHF also offers training courses to familiarize users with the fake medicines testing procedures.

We support the implementation of pharmacovigilance systems in developing countries. These systems and our regular training program ensure that patients receive products that meet international quality and safety standards. We work closely with local health authorities, national pharmacovigilance centers and pharmaceutical associations to develop and implement best practices in pharmacovigilance.



Safety Starts with Pharmacovigilance

We are implementing pharmacovigilance systems for all our marketed products in compliance with Merck KGaA, Darmstadt, Germany's Global Standards and local regulations. To date, we have eleven pharmacovigilance hubs in developing countries. Three are located in Africa, two in the Middle East, two in the Asia-Pacific and two in Latin America. In each region, we appoint a Regional Safety Manager and Local Drug Safety Officers (LDSOs), responsible for risk management and ensuring alignment with global standards and procedures. We have undertaken pharmacovigilance training of staff and third parties including in Algeria, Brazil, China, India, Indonesia, Morocco, Philippines, Thailand, Tunisia and Venezuela.

In 2013, the EMD Serono China Drug Safety team won the 'Beijing 2012 Adverse Drug Reaction Monitoring Advanced Unit' award for maintaining excellent pharmacovigilance communication with the China Food and Drug Administration (CFDA).

The problem of fake medicines is too great for us to tackle alone. We partner with key stakeholders and participate in global initiatives, such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) "Fight the Fakes" campaign. "Fight the Fakes" seeks to raise awareness about the dangers of fake medicines and to support policies reducing the proliferation of unsafe drugs. We work alongside the International Federation of Pharmaceutical Manufacturers and Associations, the NCD Alliance, the World Medical Association, The Foundation Chirac, Interpol and others who have joined the fight against fake medicines. We are an active member of the Pharmaceutical Security Institute (PSI). We support these institutions by providing research, policy support, technical advice and financial contributions in their fight against fake pharmaceuticals.

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Glossary / Definitions

Abbreviation	Definition
CePAT	Center for Pharmaceutical Advancement and Training
EPN	Ecumenical Pharmaceutical Network
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GPHF	Global Pharma Health Fund
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
LDC	Least Developed Country
MACON	Merck KGaA, Darmstadt, Germany Anti-Counterfeiting Operational Network
NCD	Non Communicable Disease
PSI	Pharmaceutical Security Institute
PQM	Promoting the Quality of Medicines Programme
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

Term	Definition
Fake medicines	Fake medicines (termed by WHO as spurious/false-ly-labelled/falsified/counterfeit medicines) are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source

